March 17, 1999

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To: Dockets Management Branch, HFA-305

From: Vivian Gilliam, HFS-215

The information enclosed should be placed in the Docket No. 94F-0334, FAP4B4430.
Environmental Assessment EA

Any additional information needed may be addressed to Vivian Gilliam at (202) 418-3167.

Sincerely,

Vivian Gilliam
Direct Additives Branch, HFS-215
Division of Petition Control
Center for Food Safety
and Applied Nutrition

Attn: Jennie Butler

94F0334

EA1

FAP 4B4430
Docket # 94F-0334

H. ENVIRONMENTAL ASSESSMENT

H.1. Date Prepared: May 24, 1995

H.2. Name of Petitioner: Morton International, Inc., Morton Plastics Additives

H.3. Address: 2000 West Street, Cincinnati, Ohio 45215

H.4. Proposed Action:

H.4.a. Morton proposes amendment of 21 CFR Part 178.2010 "Antioxidants and/or Stabilizers for Polymers" to include the safe use of the following compositions of heat stabilizer in the production of rigid PVC pipe and fittings for use in water pipe systems in food processing plants: 40-100% by weight of the reaction products of the 2-mercaptoethylester of either 9-octadecenoic acid (Z)- or a mixture of decanoic, octanoic, and tall oil fatty acids, with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS # 68442-12-6 & 151436-98-5), 0-40% by weight of 2-Mercaptoethyloleate (CAS # 59118-78-4 & 68440-24-4), 0-2% 2-Mercaptoethanol, (CAS # 00060-24-2), 0-40% by weight of Mineral Oil (CAS # 08012-95-1), 0-5% by weight of Butylated Hydroxytoluene (CAS # 00128-37-0). The pipe systems produced with the use of the stabilizer are intended to contact water that becomes a component of food products such as soups, sauces, and beverages. The abbreviated format for substances used as components of food-contact surfaces of permanent or semi-permanent equipment is being followed, in accordance with 21 C.F.R. 25.31 a(b)(2).

Approval of this group of additives in the formulation of PVC pipe will allow a lower amount of organotin stabilizer to be charged to the pipe than is typical with currently approved methyltin isooctylmercaptoacetate stabilizers, because of the higher efficiency of these new additives in pipe applications. The approval of the requested range of stabilizer compositions (see Tables 2 and 3) will allow methyltin stabilizer producers to custom formulate heat stabilizers to provide the greatest overall stability at the lowest stabilizer use level. Both these factors will minimize potential consumer and environmental exposure to the additives.

H.4.b. Morton International produces these methyltin stabilizers at 2000 West Street in Cincinnati, Ohio. This location is a suburban site with several other industrial and chemical producers adjacent to it. There is no other Morton production site for these products. The Mill Creek is adjacent to the northwest boundary of the Cincinnati Morton property. There is no effluent from this site discharged into Mill Creek.

H.4.c. Locations which may use these methyltin stabilizers include PVC compounders and PVC pipe and fitting manufacturers.

H.4.d. Ultimate disposal (after the anticipated useful lifetime of 100 years or more) of pipe and fittings made from PVC would include landfill, incineration and recycle. In the U.S., landfill is currently the most widely used option, comprising at least 90% of the disposal of PVC articles. In a landfill, leaching of the methyltin stabilizer would be expected to be very low. The additive is not very soluble in water (≤5%) and release of the additive would correspond to the very slow erosion rate of the PVC itself and its final destruction.

With regard to incineration of the PVC articles stabilized with methyltin derivatives, the tin-carbon bond will not survive the thermolytic conditions present in a commercial incinerator. Under oxidative conditions, stannic oxides, carbon dioxide, and sulfur oxides will result. It is also possible that minor amounts of mono and dimethyltin chlorides could be released upon incineration of PVC. Studies conducted to identify decomposition products upon combustion of PVC containing methyltin stabilizers are described in Appendix 14. This study shows that the only significant volatiles evolved as combustion products of methyltin stabilizer is methyltin chlorides and that the major volatiles evolved are combustion products of PVC. The use of the subject stabilizers in place of currently cleared methyltin stabilizers will have no impact on the disposal of the pipe at the end of its useful life. Furthermore, all of the potential combustion products should be efficiently removed by the scrubbing systems required for incinerators to have acceptable emission levels. In the event that traces of methyltin chlorides escape these systems, methyltin chlorides are of a very low order of toxicity by inhalation.

It is possible to recycle PVC which has been formed into final use items and, in fact, this form of recycling does occur at sites of fabrication of PVC articles, where reject PVC articles are ground into powder (regrind) and formed into new PVC articles. The percentage of post-consumer recycle of PVC articles in the U.S. is currently low (less than 1 percent). Morton is interested in increasing the amounts of PVC that are recycled and is promoting recycling and reuse programs for polymeric materials including PVC by active research programs. These programs are focused on identification of compounds that may chemically assist in the recycle of unsegregated plastic materials including PVC.

H.5. Identification of chemical substances that are the subject of the proposed action

H.5.a. Nomenclature: The commercial additives discussed in this petition are a family of products that are mixtures of a concentrated organotin heat stabilizer, commonly called Methyltin-2-Mercaptoethyloleate Sulfide (MTMEOS), and other commercial mixture ingredients listed below. The MTMEOS component may be made from either oleic acid or tall oil fatty acids that both include C_{14}-C_{18} saturated and unsaturated acids. In addition, the tall oil fatty acids may contain octanoic and decanoic acids, as described in Section A of this petition.

The other mixture ingredients include 2-Mercaptoethyloleate derived from either acid source (referred to as MEO in both cases in this document), 2-Mercaptoethanol (ME), Mineral Oil (Oil), and 2,6-Di-t-butyl-p-cresol (BHT). The molecular weights, structures and range of composition of each of these five ingredients are listed in Tables 1 and 2.

H.5.b. The CAS registry numbers and descriptions of the organotin products are:

# 68442-12-6	9-Octadecenoic acid (Z)-, 2-mercaptoethylester, reaction products with dichlorodimethylstannane, sodium sulfide (Na_2S) and trichloromethylstannane
# 151436-98-5	Dichlorodimethyl stannane and trichloromethyl stannane reaction products with 2-mercaptoethyl-decanoate, 2-mercaptoethyloctanoate, 2-mercapto-ethyltallate, and sodium sulfide.

Although this description names sodium sulfide as Na_2S, Morton charges NaSH in the presence of base. This leads to _in situ_ generation of the sulfide cation, so that the reaction products formed are the same as if Na_2S was charged. The U.S. Environmental Protection Agency (EPA) calls both NaSH and Na_2S "sodium sulfide".

CAS numbers of the non-organotin components are: MEO, 59118-78-4 & 68440-24-4; 2-mercaptoethyloctanoate; 57813-59-9, 2-mercapto-ethyldecanoate, 68928-33-6; 2-Mercaptoethanol, 00060-24-2; Oil, 08012-95-1; BHT, 00128-37-0.

H.5.c. Molecular and Structural Formulas: The molecular and structural formula of these components are shown in Table 1.

TABLE 1
MOLECULAR AND STRUCTURAL FORMULAS

Component	M.Wt.	Formula	Structural Formula
MTMEOS	Various	See below	See below
*MEO	342.7	$C_{20}H_{38}O_2S$	$CH_3(CH_2)_7CH{=}CH(CH_2)_7CO_2CH_2CH_2SH$
ME	78.1	C_2H_6OS	$HOCH_2CH_2SH$
Oil	Unspecified molecular formula		
BHT	220.4	$C_{15}H_{24}O$	

* The values shown for MEO are for a theoretical composition containing pure oleic acid. Commercial grades of oleic acid are based on natural sources containing a mixture of molecular weight acids. Based on Morton's current grade of oleic acid and the reaction purity, the average molecular weight of MEO is actually 376.

The MTMEOS organotin products are, in fact, a family of compounds as described in CAS # 68442-12-6 and 151436-98-5, formed as a result of the reactions shown below:

$$(CH_3)_xSnCl_{4-x} + HSCH_2CH_2O_2CR + NaSH \rightarrow \ldots$$

$$\begin{matrix} & CH_3 & & CH_3 & \\ & | & & | & \\ A- & Sn & -S- & Sn & -A \\ & | & & | & \\ & SR' & & SR' & \end{matrix} + (CH_3SnS)_2S + (CH_3)_2SnS + (CH_3)_xSn(SCH_2CH_2O_2CR)_{4-x}$$

Structure (I)

where x = 1 or 2, and A may be $-CH_3$, SR', or $\begin{matrix} & CH_3 & \\ & | & \\ -S- & Sn & -A \\ & | & \\ & SR' & \end{matrix}$

SR' may be $-SCH_2CH_2O_2CR$ or $-SCH_2CH_2OH$, and $HSCH_2CH_2O_2CR$ includes:

	CAS #
2-Mercaptoethyloleate	59118-78-4
2-Mercaptoethyltallate	68440-24-4
2-Mercaptoethyloctanoate	57813-59-9
2-Mercaptoethyldecanoate	68928-33-6

Structure (1) is meant to represent a group of structures that result from the reaction. The number of structures is due to possibility of different numbers of 2-mercaptoethyloleate (MEO), 2-mercaptoethanol (ME, an impurity in MEO) and sulfide ligands combining with at least two monomethyltin or dimethyltin groups. Because of the many combinations that can occur when mono- and dimethyltins are connected by a sulfide bond, an exact molecular formula cannot be written, but the average percentage of the ligands attached to tin can be described. A particular stabilizer product will be described as having a certain mono/dimethyltin ratio, and a certain mercaptide/sulfide ratio, where the ratios describe the average of all the tin ligands in the stabilizer.

H.5.d. Composition of the Additives:

TABLE 2
COMPOSITION

% Organotin products (MTMEOS)	40-100
% 2-Mercaptoethyloleate (MEO)	0-40
% 2-Mercaptoethanol	0-2
% Mineral Oil	0-40
% Butylhydroxytoluene (BHT)	0-5

The organotin products consist of mixtures of all the products resulting from the reaction shown in H.5.c. and includes products having ranges of mono- and dimethyltin groups between 10/90 to 90/10. The sulfur-containing ligands also consist of a range such that mercaptan ligands (SR') and inorganic sulfur ligands (as shown in (I)) can vary from a ratio of 65/35 to 55/45 of the tin bonds not already connected to methyl groups.

Morton would like approval to use the ranges of composition discussed above because in widely varying extrusion or injection-molding conditions, different compositions are more effective. In most pipe applications, high concentrations of monomethyltin compounds are effective. In injection molding applications, low concentrations of monomethyltin are more effective. Mercaptan synergists, antioxidants, and oil additives (with ranges described in Table 2) allow products to be formulated to the most effective stabilizer for individual formulations and extrusion equipment. This allows the stabilizer to be used at lower concentrations than if a single product formulation was available.

This ability to formulate the most efficient product formulation leads to lower stabilizer concentrations in PVC and decreased concentrations of organotin compounds extracting into potable water. This decreases the potential for consumer exposure to methyltin compounds by migration. It also means less environmental and occupational exposure to these products, and it is more cost-effective for the PVC pipe producer. Overall, the flexibility in composition of stabilizer products reduces the health and safety concerns associated with the use of these methyltin stabilizers.

H.5.e. Impurities: Lead can be present because it is a component in raw tin. The lead is known to be mostly removed from the MTMEOS products as insolubles during the intermediate reaction. It also forms insoluble salts in the final reaction step, and is filtered out of the product at the filtration step. The lead concentration in the final product has been tested by Inductively Coupled Plasma Spectrophotometry on several different commercial product formulations and was observed at less than 3 ppm in all cases.

H.5.f. Physical Properties: Physical properties of these additives are shown in Table 5 below:

Table 5
Physical Properties

Color	Amber liquid
Viscosity	36-210 cs @ 25°C
Specific Gravity	0.96-1.13 @ 25°C
Boiling Point	205-380°C
Vapor Pressure	<6-<15 mm @ 20°C
Volatiles	<1%-4% @ 110°C
Decomposition Temp.	220-380°C

These liquids are insoluble in water (≤1%) but are completely soluble in octanol. Partition coefficients determined on MTMEOS stabilizers showed K_{ow} values between 12.9 and 29.3 (Appendix 11).

H.6. Introduction of substances into the environment

H.6.a. Morton is covered by applicable requirements of OSHA, U.S. EPA, Ohio EPA and its assignees, such as the local POTW (Metropolitan Sewer District or MSD). According to data obtained as a result of a March 1995 self-compliance wastewater monitoring, Morton International, Cincinnati, Ohio, is manufacturing methyltin stabilizers in compliance with all pertinent U.S. effluent and emission requirements.

The air emissions of the only regulated process substances, methyl chloride and methyltin compounds, are well within compliance concentrations. Air emissions are controlled under a permit system required by the Ohio EPA and administered by the Hamilton County Department of Environmental Services--Air Quality Management (Air Permit Application # 1431380075 B001, P001-P026, T001-T071. These permits cover all processes and storage tanks with specific limits for volatile organic compounds (VOCs). The processes involving the production of the intermediate methyltin chloride require the achievement of a specific recovery efficiency of methyl chloride each month. Morton process control data demonstrates compliance with these requirements.

All solid and liquid wastes are managed in compliance with federal (RCRA), state, and local regulations. Solid waste is landfilled at EPA approved secure facilities. The current amount of landfilled waste is less than 0.013 pounds per pound of stabilizer manufactured. This solid waste contains only one substance that is a defined environmental hazard, lead. The concentration of lead in this waste has been significantly decreased through improved raw material sources and process control. This reduction of lead is such that the solid waste is **not** a RCRA hazardous waste by characteristic (D008).

Process Water discharges to the POTW, while comprising the largest volume of waste from all the intermediate and stabilizer process steps, contain few regulated compounds. All process, sanitary, and stormwater from the facility is discharged to the local publicly owned treatment works (POTW), under a permit issued by the Metropolitan Sewer District (MSD, permit number MIL-026, issued December 29, 1992). The discharges to the POTW are covered by the pre-treatment standards for Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) regulations plus applicable local POTW limits. The OCPSF regulations cover 31 listed organic pollutants. The local regulations cover, as surcharge components, Total Suspended Solids (TSS), Biological Oxygen Demand (BOD), and Total Kjeldahl Nitrogen (TKN). The POTW also has local limits for pH, metals, cyanide, phenols, and non-biodegradable oil and grease. This water is monitored regularly by MSD to assure compliance and to determine a current surcharge rate. In addition, Morton conducts required periodic self-monitoring for determining compliance with the OCPSF organic pollutants. The concentrations of these were shown to be in compliance with all the pertinent regulations during the March 1995 self-compliance monitoring.

In 1985, Morton installed a groundwater collection system consisting of a French drain and slurry wall to intercept and treat potentially contaminated groundwater. This system was designed to prevent migration onto the site from an adjacent Superfund site, as well as prevent off-site migration. This system was not required by any government agency. Morton groundwater wells are monitored as required by regulatory agencies such as the USEPA. The recovered groundwater is carbon-treated and used as make-up water for the Morton's recirculating cooling water system.

In summary, Morton uses many control procedures to minimize emissions to the environment, and to minimize the amount of material that must be disposed of by approved methods, including the amount of RCRA hazardous waste. These controls have increased over the last six years so that the amounts of emitted or buried waste have been reduced significantly. Approval of this additive for use in food processing plant water pipes would have no effect on compliance with all emission regulations and will not increase amounts of process waters discharged from Morton's stabilizer production facility.

Mr. G. E. Schaaf, Manager of Health, Safety, and Environmental, hereby certifies that, to the best of his knowledge and according to data obtained as a result of an March 1995 self-compliance wastewater monitoring, Morton International, Cincinnati, Ohio, is manufacturing methyltin stabilizers in compliance with all pertinent U.S. effluent and emission requirements.

H.6.b. The estimated maximum yearly U.S. market volume of the proposed MTMEOS stabilizers for food processing plant use is about 500,000 pounds, assuming these methyltin stabilizers capture the entire food processing water PVC pipe market.

In general, no stabilizer is lost during compounding operations and any offgrade compound or finished products are recycled so that virtually all of the PVC and associated additives are included in finished pipe or fittings. For purposes of calculation, the EPA estimate of 0.01% loss in PVC fabrication plants from spillage or residue in discarded containers will be used (Federal Register 48(217):51363, November 8, 1983). This factor indicates that, in the worst case, 50 pounds of methyltin stabilizer may potentially be released to the environment from this source annually. This total would be spread out among all U.S. PVC compounders and fabricators using the proposed methyltin stabilizers, whose number is potentially 10 or more.

H.6.c. OSHA regulates many chemicals for concentrations in air under 29 CFR 1910.1000, Table Z-1-A. Organotin compounds are regulated with an OSHA permissible exposure limit (PEL) of 0.1 mg/m^3 (measured as tin). Morton routinely conducts industrial hygiene monitoring in areas where methyltin chlorides are handled in order to verify the tin concentrations in the workplace are less than the PEL. Areas where the final stabilizer product is handled are monitored on occasion, although concern about tin inhalation exposure from this route is of less concern, since the product is non-volatile (less than 0.1 mg/m^3), and would not present a health and safety hazard under normal use conditions.

H.7. Fate of emitted substances into the environment: documentation of environmental fate is not normally required for components of permanent or semi-permanent equipment under 21 CFR 25.31 a(b)(2).

H.8. Environmental effects of released substance: documentation of environmental effects is not normally required for components of permanent or semi-permanent equipment under 21 CFR 25.31 a(b)(2).

H.9. The proposed methyltin-2-mercaptoethyloleate sulfide additives are intended for the same use as methyltin isooctylmercaptoacetates (21 CFR 178.2010) already in use. This use of methyltin compounds as heat stabilizers for pipe in food processing plants does not represent a new use for PVC pipe. These MTMEOS products are more efficient stabilizers in PVC pipe formulations and are intended to be used in place of the currently approved methyltin compounds for this use. By replacing these with the more efficient compounds described in this petition, lower use levels can be effected.

H.10. Mitigation measures: documentation is normally not required for this type of food additive.

H.11. Alternatives to the proposed action: documentation is not normally required for this type of food additive.

H.12. List of preparers:

Mary Rita Dominic[1], Senior Manager of Analytical Services, Morton International, 2000 West Street, Cincinnati, Ohio 45215,(513-733-2141, FAX 513-733-2115). Holds B.A. and M.S. in Analytical Chemistry. Expertise in structural analysis, instrumental analysis, wet chemistry, and trace determinations. Has been employed by Morton International for 16 years.

Thomas G. Kugele, Vice President R&D and Technical Director, Morton International. Holds Ph.D. in Organic Chemistry. Expertise in organic synthesis, especially organotin mercaptides. Has been employed by Morton International for 29 years.

Glenn E. Schaaf, P.E., Manager, Health, Safety & Environmental. Holds A.B. Pre-Engineering, B.S. Industrial Engineering, MBA Industrial Management and is Certified in Hazardous Waste. Expertise in health, safety, environmental and regulatory affairs. Has been employed by Morton International for 25 years.

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[1]Author to whom all correspondence should be addressed.

H.13. Certification: The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Morton International.

Mary Rita Dominic

Senior Manager of Analytical Services

May 24, 1995

14. References - see Appendices

15. Appendices

    1. Toxicological Data on MTMEOS and MEO

       Previously submitted with Threshold of Regulation request:

Cannon 8E-3123	Hill Top 74-438-21
Cannon 8E-2521	SRI 7692-A08-90
CIVO R5716	SRI 7692-C09-90
CIVO R4674	SRI 7692-T08-90

       Add:

CIVO 4740	**CIVO 4737**
Hill Top 81-0399	**Hill Top 86-0231**

    11. Health Effects and Solubility of Methyltin Compounds

    14. Study of Catastrophic Heat Decomposition Products from PVC (Morton, 1993)